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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/801,389	03/12/2004	Frank W.R. Chaplen	245-67734-01	3168

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EXAMINER
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SIMS, JASON M

ART UNIT	PAPER NUMBER
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1631

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05/31/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/801,389	<b>Applicant(s)</b> CHAPLEN ET AL.	
	<b>Examiner</b> Jason M. Sims	<b>Art Unit</b> 1631	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 March 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,2,7-22,80-83,108-110,115,118 and 119 is/are pending in the application.
- 4a) Of the above claim(s) 3-6,11,28-77,79,84-107,112-114,116 and 117 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,7-22,80-83,108-110,115,118 and 119 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Applicant's arguments, filed 3/5/2007, have been fully considered but they are not deemed to be persuasive. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Applicants have amended their claims, filed 3/5/2007, and therefore rejections newly made in the instant office action have been necessitated by amendment.

Applicant's cancellation of claims 23-27 and 78 in the reply filed on 3/5/2007 is acknowledged.

Applicant has newly added claims 118-119, which have been entered.

Claims 1-2, 7-22, 80-83, 108-110, 115, and 118-119 are the current claims hereby under examination.

#### ***Claim Rejections - 35 USC § 112***

The rejection of claim 1 under 35 USC 112 second paragraph for containing the word "representing" has been withdrawn because of applicant's amendment.

Applicant has stated that claims 8 and 9 have been amended to delete the term "software," but no such deletion has been indicated in the claims filed 3/5/2007. However, applicant's amendment has explicitly defined the term "expert" and adequate support for the definition of said "expert" has been pointed out by applicant and therefore the rejection of claims 8 and 9 under 35 USC 112 second paragraph for containing the wording "software expert parameters" and "expert parameters" has been withdrawn.

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Applicant's arguments and amendment with respect to the rejection of claims 11, 17-18, 23, and 26 under 35 USC 112 second paragraph for containing the vague and indefinite wording of "simplex scenarios" has been found persuasive and the rejection has been withdrawn.

Applicant has stated that claims 13 and 15 have been amended to delete the term "software," but no such deletion has been indicated in the claims filed 3/5/2007. However, applicant's arguments and amendment with respect to the rejection of claims 13 and 15 under 35 USC 112 second paragraph for containing the vague and indefinite wording of "software experts" has been found persuasive and the rejection has been withdrawn.

The rejection of claims 16, 24, and 27 under 35 USC 112 second paragraph for containing the vague and indefinite wording "complex scenarios" has been withdrawn because of applicant's amendment.

The rejection of claim 18 under 35 USC 112 second paragraph for containing the vague and indefinite wording "where each simplex scenario is an elicitor" has been withdrawn because of applicant's amendment.

The following are new rejections made under 35 USC 112 second paragraph, which have been necessitated by amendment.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1-2, 7-22, 78, 80-83, 108-110, 115, and 118-119 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, lines 1-2, recite "a method for classifying an unknown bioactive condition" in the preamble while the method steps, lines 3-9 are directed to attempting to classify a scenario, which causes claim 1 to be vague and indefinite. The metes and bounds of claim 1 is not clear because it is not clear whether the preamble reciting "a method for classifying an unknown bioactive condition", or the method steps control the metes and bounds of said claim 1.

Claim 1 contains the word "determining data," which is deemed as vague and indefinite. It is unclear as to what exactly the wording "determining data" refers. Clearer claim wording is required.

Claim 1 contains the word "sufficient," which is deemed as vague and indefinite. It appears that the word "sufficient" may refer to a quantitative or qualitative value. Clearer claim wording is required.

Claim 1 recites the limitation "the system" in line 6. There is insufficient antecedent basis for this limitation in the claim.

Claim 7 contains the wording "the database being generated by exposing a biological system to known scenarios" at line 4, which has been deemed as vague and indefinite. It is unclear how the exposure of a biological system to known scenarios generates a database. In addition, at line 3, a database is provided. It is also vague

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and indefinite as to how a provided database is being generated after said database has been provided. Clearer claim wording is required.

Claim 16 contains the wording "following mathematical transformation," which has been deemed as vague and indefinite. It is unclear as to what exactly "following mathematical transformation" refers. Clearer claim wording is required.

Claims 2, 8-15, 17-22, 78, 80-83, 108-110, 115, and 118-119 are rejected as being dependent from a rejected claim.

***Claim Rejections - 35 USC § 101***

The rejection of claims 1, 7-27, 78, and 80-83 under 35 USC 101 has been withdrawn because of applicant's amendment to the claims.

***Claim Rejections - 35 USC § 102***

Applicants arguments with respect to the rejection of claims 1-2, 7, 12-16, 80-82, and 108-110 under 35 USC 102 are not found to be persuasive.

Applicant argues the claimed scenario is generated by exposing biological systems to two or more bioactive conditions whereas the '916 patent exposes a biological system to a single pharmaceutical or nutraceutical.

Applicant's allegations are not persuasive because in the abstract, the '916 patent specifically states that the biological condition may be responsive to treatment of one or more agents and therefore clearly reads on a biological system exposed to two or more bioactive conditions.

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Applicant further argues that the '916 patent solely teaches a numerical approach and does not include the possibility of non-numerical features.

Applicant's argument is not found persuasive because the '916 patent, which teaches generating a feature space vector that includes numerical features reads on the broad interpretation of the wording "a feature space vector," which is not limited to having to include both numerical and non-numerical features.

The following rejection has been maintained.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-2, 7, 12-16, 80-82, 108-110, 118-119 are rejected under 35 U.S.C. 102(e) as being anticipated by Bevilacqua et al. (US P/N 6,692,916). Can you

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reject claims 118 and 119 with this patent? Looks like '916 teaches 118, at least. It's up to you☺

The claims are directed to a method of classifying a scenario, comprising exposing a system to a bioactive condition, representing a response of the system, or portion thereof, to the bioactive condition; and attempting to classify a scenario by database comparison.

Bevilacqua et al. teaches claims 1-2 and 118-119 at the abstract, at col. 2, lines 34-67, col. 3, and col. 4, lines 1-14. Bevilacqua et al. discusses a method for evaluating the effect on a biological condition affected by an agent and another method for evaluating the effect on a biological condition by a first agent in relation to the effect by a second agent, which the target cells that were administered the agents represent the exposed system as cited in claims 1 and 2 and the agents administered to the target cells represents the bioactive condition to which the system is exposed. Bevilacqua et al. further discusses making calibrated profile data sets that correspond to a measure of the biological condition as affected by the agent, which represents representing a response of the system to the bioactive condition. Bevilacqua et al., at the abstract, discusses a method for evaluating a biological condition of a subject using a calibrated profile data set, which represents classifying the scenario by database comparison. Bevilacqua et al. further discusses the evaluation being a database comparison at col. 4, where evaluating is a comparison of the first instance of the calibrated profile data set in relation to the data in the condition database, which represents classifying a scenario by database comparison. Additionally, Bevilacqua et al. discusses exposing a biological



system to two or more bioactive conditions consecutively and where numerical and non-numerical feature descriptors are obtained.

Bevilacqua et al. teaches claim 7 at col. 4, lines 1-50. Bevilacqua et al. teaches comprising profile data sets, which provide measurements of the biological condition in response to system being exposed to an agent, such as RNA, protein, or numerical gene expression values, which all represent data sufficient to determine a numerical feature space vector. Bevilacqua et al. further teaches using a condition database, where the records are from a population of subjects from known scenarios, for comparing the measured values as a result of the exposure in order to evaluate the resulting biological condition, which represents providing a database for comparison by exposing a system to known scenarios to determine a numerical feature space vector. Bevilacqua et al. also teaches transforming the profile data set to a calibrated profile data set, which represents transforming the data.

Bevilacqua et al. teaches claims 12-16 and 80-82 at col. 18, lines 53-67, col. 19-21, col. 22, lines 1-62, col. 24, lines 16-49, and col. 25, lines 25-30. Bevilacqua et al. teaches at col. 22, lines 57-62, generating signature profiles for different scenarios. At col. 19-21, Bevilacqua et al. teaches extracting the data and creating calibrated profiles and signature panels, which represent calculated locations in feature space representing the characteristic signature of the bioactive condition. Bevilacqua et al. col. 25, teaches using the calibrated profile data sets to determine likelihood that a bioactive condition is a known bioactive condition. Bevilacqua et al. at col. 22, teaches generating signature panels about a previously undescribed agent and may be derived

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optionally together with a signature profile to use as a gold standard, which is comparing the standard against those panels created later for determining a likelihood that a complex scenario is a scenario. Bevilacqua et al. at col. 24, lines 16-49, teaches that the invention is automated on a computer program, which inherently reads on calculating relative location of data clusters using software experts.

Bevilacqua et al. teaches claims 108-110, at col. 24, lines 16-49. Bevilacqua et al. discusses the invention being implemented on a computer program and fixed on a tangible medium such as a computer readable medium, for use in a computer system.

### **Conclusion**

**No claim is allowed.**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jason Sims, whose telephone number is (571)-272-7540.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ram Shukla can be reached via telephone (571)-272-0735.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

// Jason Sims //

*See H. Claw*  
*Primary Patent Examiner*  
*5/29/07*